Complete Summary

GUIDELINE TITLE

Control and prevention of rubella: evaluation and management of suspected outbreaks, rubella in pregnant women, and surveillance for congenital rubella syndrome.

BIBLIOGRAPHIC SOURCE(S)

Control and prevention of rubella: evaluation and management of suspected outbreaks, rubella in pregnant women, and surveillance for congenital rubella syndrome. MMWR Recomm Rep 2001 Jul 13;50(RR-12):1-23. [22 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Rubella (suspected rubella outbreaks, rubella in pregnant women, and congenital rubella syndrome)

GUIDELINE CATEGORY

Evaluation
Management
Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Nurses
Patients
Physician Assistants
Physicians
Public Health Departments

GUIDELINE OBJECTIVE(S)

- To describe seven steps for evaluating and managing suspected rubella outbreaks
- To provide guidelines for evaluating and managing rubella in pregnant and nonpregnant women and evaluating infants for congenital rubella infection

TARGET POPULATION

- Individuals exposed to rubella, particularly pregnant women
- Infants born to women infected with rubella

INTERVENTIONS AND PRACTICES CONSIDERED

Ascertainment and Management of Suspected Outbreaks of Rubella

1. Ascertainment of rubella cases in the workplace and community, including searching documentation (medical records, payroll or sick leave), contacting schools and day care centers, and conducting follow-up interviews with workers and their contacts, and thorough investigation of patient contacts.
2. Laboratory testing to confirm diagnosis of rubella, such as serological testing for rubella immunoglobulin M (IgM) and immunoglobulin G (IgG) antibodies, isolation of rubella virus from clinical specimens, or detection of virus by reverse transcriptase polymerase chain reaction.
3. Conducting case investigations, identifying contacts, and vaccination of all susceptible contacts.
4. Institution of enhanced active and passive surveillance measures to identify cases prospectively and retrospectively.
5. Implementation of rubella control measures, especially in congregate environments and healthcare settings.
6. Conducting outreach activities in affected workplace environments and within the community.

7. Developing a plan for preventing future rubella outbreaks, such as ensuring high levels of rubella immunity, vaccination of susceptible persons, maintaining rubella and congenital rubella syndrome surveillance and reporting, and preparing an appropriate and rapid response when a case of rubella is identified.

Rubella Prevention and Control among Women of Childbearing Age

1. Routine determination of rubella immunity in women of childbearing age and vaccination of those who are susceptible and not pregnant.
2. Routine rubella immunoglobulin G testing in all pregnant women without likely exposure (note: the toxoplasmosis, rubella, cytomegalovirus, and herpes [TORCH] panel is considered by not recommended).
3. Screening and follow-up of pregnant women who might have been exposed to rubella, including documented serologic testing and counseling (note: administration of vaccine to pregnant women is not specifically contraindicated).

Surveillance for Congenital Rubella Syndrome

1. Following pregnancy outcome in women with confirmed or suspected rubella.
2. Education of health care providers about the potential for congenital rubella syndrome.
3. Follow-up and reporting of all confirmed cases of congenital rubella syndrome.

MAJOR OUTCOMES CONSIDERED

- Incidence of suspected outbreaks of rubella, rubella in pregnant women, congenital rubella syndrome, and congenital rubella infection
- Morbidity and mortality due to outbreaks of rubella, rubella in pregnant women, congenital rubella syndrome, and congenital rubella infection

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Evaluation, Management, and Surveillance of Suspected Rubella Outbreaks

The seven steps described in this section are recommended for the evaluation, management, and surveillance of suspected rubella outbreaks. They are based on recent experience with outbreaks in the United States. These recommendations can be used in settings beyond those discussed in the original guideline document.

Consider a Single Case of Rubella a Potential Outbreak

Because the incidence of rubella is low in the United States, health agencies should consider even one case a potential outbreak. Rubella is an infectious disease for which 20% to 50% of cases are asymptomatic, and investigation of an apparently isolated case could reveal additional cases. Rubella transmission can occur in congregate settings such as households, workplaces, universities, jails, or communities. The type and size of the outbreak determines the magnitude of the response.

Most recent rubella outbreaks were first identified in the workplace. Facilities that employ many foreign-born workers (e.g., meat or poultry processing plants) are at greater risk for rubella outbreaks than those with mostly workers born in the United States. Initial reports can come from on-site health-care providers who have recently seen rash illness among employees.

Steps to Improve Ascertainment of Rubella Cases in the Workplace

- Search on-site medical logs for rash illness and payroll or sick leave documentation for workers who might have been absent because of illness.
- Conduct follow-up interviews with workers who have been sick and contacts to determine history of recent rash illness.

Steps to Improve Ascertainment of Rubella Cases in the Community

Recently, investigations of workplace outbreaks have revealed spread to the community. The following steps can help identify cases in the community:

- Review the community demographics to determine if there are groups at high risk for not being vaccinated (e.g., foreign-born persons or members of religious communities opposed to vaccination).
- Search medical records of the community's health-care providers and hospital emergency rooms.
- Contact schools and day care centers to identify absences caused by rash illness.
- Conduct thorough follow-up investigation of patient contacts, including household residents, students, and teachers.

Confirm the Diagnosis

Because rubella has many symptoms in common with other rash illnesses, laboratory confirmation is required for case confirmation. Laboratory testing should be conducted for all suspected cases of rubella. Immunoglobulin M antibodies might not be detectable before 4 to 5 days after rash onset. If negative rubella immunoglobulin M and immunoglobulin G results are obtained from specimens taken before 4 to 5 days, repeat serologic testing.

Conduct Case Investigations and Vaccinate Susceptible Contacts

Case investigation and identification of contacts should be conducted for all suspected cases of rubella. In addition, asymptomatic confirmed cases should be investigated and contacts identified. A descriptive analysis of an outbreak allows health agencies to focus control measures, especially vaccination, on persons

most in need. Cases of rubella occurring in vaccinated persons within 7 to 10 days after vaccination should be investigated, and specimens should be obtained for virus isolation to determine if rash is attributable to vaccine virus or wild virus. Any direct contact with a patient with rubella during the infectious period (i.e., 7 days before, to 5 to 7 days after rash onset) is defined as exposure. Contact can include (but is not limited to) living in the same household, attending the same class or social function, or working side-by-side on a production line. Although rubella transmission is usually associated with repeated exposure, transmission has been documented after a single exposure.

Depending on resources available, investigation of contacts of patients with rubella might need to be prioritized based on the probability of transmission. The first priority should be persons who share households or persons in a congregate environment who share space (e.g., side-by-side workers on a production line) with a patient. The second priority should be persons who share or have shared environments with a potential for contact (e.g., places of worship, parties, social gatherings), but who did not knowingly have direct contact with a patient. If resources allow, investigation of contacts can be extended to geographic areas or groups at risk where disease has been documented. Every effort should be made to identify all susceptible pregnant women who might have been exposed to a patient and test them for rubella immunity. For example, in a workplace outbreak, pregnant women who have contact with patients (including coworkers and household contacts) should be evaluated for rubella immunity. In community wide outbreaks, health-care workers who treat pregnant women should be alerted to the outbreak and advised to verify rubella immunity in pregnant women.

Steps for Locating Exposed Contacts for Further Investigation

- Record symptom onset date and infectious period for patients on a calendar to determine in what setting the exposure might have occurred, where to look for other exposed persons, and who suspected patients had contact with during their infectious period. For example, if a person had rash onset January 26, exposure would have occurred 12 to 23 days earlier (i.e., January 3 to 14). The patient would have been infectious from 7 days before, to 5 to 7 days after rash onset (i.e., January 19 to February 3). Consider asymptomatic confirmed patients infectious 5 to 30 days after the last exposure.
- Use the calendar to list contacts identified during the infectious period.
- Follow up with contacts to assess symptoms of rubella-like illness, determine susceptibility, and vaccinate susceptible persons without adequate proof of immunity and who have no contraindications to rubella vaccine.
- Continue to investigate contacts of subsequently identified patients. (See the section titled "Rubella Prevention and Control Among Women of Childbearing Age," below, for information on follow-up of pregnant contacts.)

Information That Should Be Obtained from Patients With Rubella

- Name, address, and telephone number(s) to reach the patient after the initial interview, if necessary.
- Demographic information, including country of origin, length of time in the United States, and length of time in the state where the rubella diagnosis was made.
- Primary language spoken.

- Clinical details, including the following:
    - Date of onset and duration of rash
    - Presence of other symptoms (e.g., fever, arthralgia/arthritis, lymphadenopathy, conjunctivitis) and date of onset
    - Complications (e.g., encephalitis, thrombocytopenia, death)
- Vaccination status, including the following:
    - Number of doses of rubella vaccine
    - Dates of vaccination
    - If not vaccinated, reason for nonvaccination
- Risk factors for disease, including the following:
    - Contact with a probable or confirmed patient or a person with a rash illness suspected of being rubella
    - Transmission setting (e.g., day care center, school, workplace, place of worship, athletic event, or other congregate or social gathering)
    - Relationship to outbreak (i.e., whether case is sporadic or part of an identified outbreak)
    - Travel history
    - Contact with others who have recently traveled (i.e., import status [indigenous, state-to-state, or international], state name, and country name [and state within the country])
- Information regarding contacts during the infectious period (i.e., 7 days before, to 5 to 7 days after rash onset), including the following:
    - List of persons with household contact (e.g., residents and others with close contact in the home) and persons with contact in a congregate environment with shared space
    - List of women who are pregnant who have had contact with a patient with rubella
    - Rubella symptoms (e.g., rash, fever, lymphadenopathy) of contacts
    - Place of employment of contacts
- Laboratory information, including the following:
    - Date and source of specimen sent for viral culture (e.g., throat, urine, blood)
    - Viral culture results (positive or negative for rubella virus)
    - Serologic test results for serum rubella immunoglobulin M or immunoglobulin G, with specific titer results when applicable (e.g., 1:256). A positive serum rubella immunoglobulin M or a significant rise between acute- and convalescent-phase immunoglobulin G titers indicates an acute infection
- Pregnancy status of female patients, including the following:
    - Whether pregnant
    - If patient is pregnant, obtain information regarding (a) number of weeks of gestation at onset of illness; (b) previous evidence or date of serological immunity; (c) previously diagnosed rubella infection and date; (d) date and specific titer result of previous serum rubella immunoglobulin G titer; and (e) pregnancy outcome, when available

Enhance Active and Passive Surveillance Measures

- For this step, outbreak investigators should institute surveillance measures designed to identify cases prospectively, as well as any cases with rash onset that preceded the first identified case. Because some persons with rubella do not have rash, these measures should use a broader definition of suspected

cases (e.g., fever with lymphadenopathy or arthralgia/arthritis in adult women) in areas where rubella cases have been confirmed. Broadening the case definition and investigating suspected cases could lead to more complete ascertainment.

Components of Surveillance for Rubella in an Outbreak Setting

- Identify health-care providers and facilities serving populations at risk and involve them in surveillance.
- Identify workplaces with large numbers of persons who might lack rubella immunity and involve them in surveillance.
- Identify day cares, schools, places of worship, and community organizations (particularly in neighborhoods where many residents might lack rubella immunity) and involve them in surveillance.
- Promote awareness among health-care providers that rubella and congenital rubella syndrome still occur in the United States among certain groups that lack rubella immunity.
- Distribute written guidelines instructing health-care providers to obtain appropriate serology and specimens and to notify health departments of all suspected rubella cases.
- Establish routine contact (e.g., daily or weekly) with hospitals, doctors' offices, clinics, schools, and laboratories to obtain reports of persons with rash illness or other symptoms indicative of rubella.

In addition to prospective surveillance, retrospective case finding should be conducted for 6 weeks (i.e., two incubation periods) before the first identified case. If evidence indicates that the outbreak was in progress during this time, retrospective case finding should continue until no further cases are identified.

Steps to Identify Cases Retrospectively

- Review medical records in health-care settings, including doctors' offices, for rubella-like illness.
- Review workplace or school absentee logs.
- Review records of laboratories that conduct testing for the area.

Implement Rubella Control Measures

During a rubella outbreak, the following control measures should be taken:

- Isolate patients for 5 to 7 days after rash onset.
- Identify and vaccinate susceptible persons who have no contraindications to rubella vaccine.
- Ensure that pregnant women who are exposed to rubella and do not have adequate proof of immunity are serologically evaluated for rubella-specific immunoglobulin M and immunoglobulin G antibodies (see the section titled "Laboratory Diagnosis of Rubella" in the original guideline document).
- Counsel susceptible pregnant women regarding the risks for intrauterine rubella infection and recommend that they restrict their contact with persons with confirmed, probable, or suspected rubella for 6 weeks or longer (two incubation periods) after rash onset in the last identified patient. Pregnant women should also be advised to avoid activities where they might be

exposed to rubella for 6 weeks (two incubation periods) after the onset of symptoms of rubella in the last patient for whom rubella cannot be ruled out to minimize their chances of coming in contact with persons with symptomatic or asymptomatic rubella infection (see the section titled "Rubella Prevention and Control Among Women of Childbearing Age," below).

Control Measures for Specific Settings

Congregate Environments. Congregate environments include households, jails, day cares, schools, military settings, workplaces, places of worship, athletic events, and other social gatherings. Control measures recommended for these settings are as follows:

- Refer persons without adequate proof of rubella immunity for vaccination or offer on-site vaccination clinics. After vaccination, these persons no longer need to restrict contact. The exception is health-care workers (see the section titled "Health-Care Settings," below).
- Isolate patients during their infectious period (i.e., 5 to 7 days after rash onset). Recommend that patients restrict contact with pregnant women and persons without adequate proof of rubella immunity for 5 to 7 days after rash onset.
- Recommend for day cares and schools that persons exempt from rubella vaccination for medical, religious, or other reasons be excluded from attendance for 3 weeks after onset of rash in the last reported patient in the outbreak setting.
- Recommend that all susceptible persons who were not vaccinated as part of the control efforts (e.g., those who refused vaccination or who had contraindications to vaccine) minimize contact with patients for 5 to 7 days after rash onset.
- Recommend that susceptible pregnant women not attend activities, particularly in the first trimester of pregnancy, where they might be exposed to rubella for 6 weeks or longer (two incubation periods) after the onset of symptoms of rubella in the last patient for whom rubella cannot be ruled out to minimize their chances of coming in contact with persons with asymptomatic rubella infection.

Health-Care Settings. Health-care settings include hospitals, doctors' offices, clinics, nursing homes, and other facilities where patients receive subacute or extended care. Control measures recommended for these settings include excluding and vaccinating health-care workers without adequate evidence of immunity, particularly in settings where pregnant women could be exposed. All persons who work in health-care facilities or who have contact with any patients should be immune to rubella. Any exposed health-care worker who does not have adequate evidence of immunity should be excluded from duty beginning 7 days after exposure to rubella and continuing through either (a) 21 days after last exposure or (b) 5 to 7 days after rash appears. Susceptible, exposed health-care workers who are vaccinated should be excluded from direct patient care for 23 days (i.e., the longest incubation period) after the last exposure to rubella because no evidence exists that postexposure vaccination is effective in preventing rubella infection in persons already infected at the time of vaccination. Because birth before 1957 does not guarantee immunity, health-care facilities

should strongly recommend a dose of measles-mumps-rubella (MMR) vaccine to workers born before 1957 who do not have serologic evidence of immunity.

Community-wide Rubella Outbreaks. When community-wide outbreaks occur, the following steps are recommended:

- Attempt to ensure proper isolation procedures for all patients. In general, any person exposed to a patient with rubella or congenital rubella syndrome who cannot demonstrate proof of immunity should receive vaccine or restrict contact with patients with rubella or congenital rubella syndrome.
- Make every effort to identify and test all exposed pregnant women. In community-wide outbreaks, health-care workers who treat pregnant women should be alerted to the outbreak and advised to verify rubella immunity in pregnant women (see the section titled "Rubella Prevention and Control Among Women of Childbearing Age," below).

Conduct Outreach in Affected Facilities and Communities

Outreach activities should begin during the outbreak investigation and should convey the seriousness of rubella infection and the importance of rubella vaccination and other control efforts. Outreach activities also provide an opportunity to reinforce the importance of persons seeking medical advice for rubella-like illnesses and of health-care workers reporting rubella.

Workplace

In the workplace, outreach activities should focus on educating workers and employers regarding rubella and its consequences, using such strategies as educational sessions, flyers, letters, and E-mail. Stress that persons who work in a place where an outbreak is in progress and who live with or have contact with someone who is pregnant should be vaccinated unless known to be immune.

Community

A community-wide outbreak can be most effectively contained if public health agencies form partnerships with community leaders, health-care providers, and groups with a history of effective community involvement. These persons can act as liaisons between public health agencies and the community. Outreach activities in the community should include the following:

- Identifying persons in the community who can serve as liaisons between public health agencies and the local population (e.g., community activist groups, members of the foreign-born community, health-care workers who treat migrant populations, and leaders in places of worship).
- Training these liaisons on the current epidemiology and clinical symptoms of rubella, as well as laboratory testing methods (for health-care providers). Stress the importance of vaccinating persons who are susceptible to rubella, particularly persons who live in households with pregnant women or any women of childbearing age.
- Working with liaisons to develop targeted education messages and materials that address community members' beliefs regarding health care. Distribute

messages and materials where community members who are at risk are likely to have access to them.
- Encouraging liaisons to participate in surveillance activities (e.g., they could be aware of persons in community organizations who have missed activities because of illness).
- Establishing vaccination sites in areas frequented by the local population (e.g., places of worship, day labor pick-up sites, worksites, or places where special celebrations are held) and providing counseling on the importance of rubella vaccination. Bilingual personnel might be needed to serve as counselors and investigators at these sites.

Develop a Plan for Preventing Future Rubella Outbreaks

Prevention of future rubella outbreaks includes ensuring high levels of rubella immunity, vaccinating susceptible persons, maintaining rubella and congenital rubella syndrome surveillance and reporting, and preparing an appropriate and rapid response when a case of rubella is identified. To make the most effective use of resources to prevent congenital rubella syndrome and control rubella, state and local health authorities might want to identify and prioritize counties and communities in order of decreasing risk and conduct vaccination or education campaigns accordingly. Depending on cost and available resources, health department personnel might decide to target all counties and communities in the state or limit the campaigns to those at highest risk for rubella outbreaks based on known or suspected susceptibility patterns and the likelihood of introduction of rubella into the community. Based on the current epidemiology of rubella, counties most at risk appear to be those with substantial numbers of adolescents and young adults born and raised in countries that do not have a history of routine rubella vaccination.

All states should conduct activities for the prevention of congenital rubella syndrome or congenital rubella infection, including the following:

- Identifying women of childbearing age at risk for rubella infection and ensuring immunity in women by enhancing existing programs (e.g., prenatal testing and postpartum vaccination). Approximately 50% of congenital rubella syndrome cases could be prevented through postpartum vaccination of women known to be susceptible to rubella.
- Maintaining rubella surveillance and investigating contacts of patients appropriately.
- Providing ethnically and linguistically appropriate rubella educational materials where persons susceptible to rubella might congregate (e.g., worksites; health clinics; women, infants, and children [WIC] centers; and community centers).
- Ensuring that measles-mumps-rubella vaccine is available to providers through the Vaccines for Children (VFC) program or the 317 Immunization Grant Program (under the U.S. Public Health Service Act). For more information on these programs, contact the U.S. Centers for Disease Control and Prevention's National Immunization Program, Immunization Services Division, Program Operations Branch at (404) 639-8215 (United States only); Web site, www.cdc.gov/nip.

In addition, states in the U.S. that have had recent rubella outbreaks or a recent indigenous congenital rubella syndrome case or that have identified populations at high risk for rubella outbreaks might want to emphasize rubella control as well as congenital rubella syndrome prevention through the following activities:

- Ensuring immunity among all persons (male and female), especially foreign-born persons who are not likely to have received rubella vaccination.
- Educating providers, especially "Vaccines for Children" program providers, regarding the potential increased risk for rubella susceptibility among foreign-born persons and ensuring that providers recommend vaccine for susceptible persons.

At workplaces where recent rubella outbreaks have occurred or high numbers of persons at risk for rubella are employed, state health departments should:

- Educate management and workers regarding the risks for rubella and congenital rubella syndrome.
- Recommend that all employees susceptible to rubella receive measles-mumps rubella vaccine.
- Recommend that rubella immunization be provided in the workplace. Some states might consider conducting projects to demonstrate the feasibility of rubella immunization in the workplace.
- Ensure that workers who are vaccinated receive personal immunization record cards.
- Ensure that family members and close personal contacts of susceptible workers are referred to the health department or other provider for immunization.

In communities that have had recent rubella outbreaks or where large numbers of persons at risk for rubella reside, state health departments should:

- Identify leaders in communities at risk to serve as spokespersons for rubella control and congenital rubella syndrome prevention programs.
- Work with community groups (i.e., civic or faith-based organizations) to conduct education programs and vaccination campaigns.
- Encourage employers to establish a rubella screening and vaccination program for all current and new employees.
- Provide necessary vaccines for group members at risk identified in public health clinics.
- Alert other state health departments of rubella outbreaks, particularly those with evidence of state-to-state importation.

Vaccine

This section summarizes information available in the 1998 U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) statement on measles-mumps-rubella vaccination (MMWR Morb Mortal Wkly Rep 1998 May 22;47[RR-8]:1-57; see the related National Guideline Clearinghouse [NGC] Guideline Summary). In the United States, most rubella vaccination is administered as part of the measles-mumps-rubella vaccine. Approximately 21 to 28 days are required for development of protection following vaccination.

Persons generally are presumed immune to rubella if they (a) have documentation of vaccination with ≥1 dose of measles-mumps-rubella or other live, rubella-containing vaccine administered on or after the first birthday, (b) have laboratory evidence of immunity, or (c) were born before 1957 (except women who could become pregnant). Susceptible adults born after 1957 who do not have a medical contraindication should receive ≥1 dose of measles-mumps-rubella vaccine for protection against rubella and two doses ≥ 1 month apart if at high risk for exposure to measles. Birth before 1957 is not acceptable evidence for rubella immunity for women who could become pregnant.

Contraindications and Precautions

See the field labeled "Contraindications" (in the National Guideline Clearinghouse (NGC) Complete Guideline Summary for this guideline) for more information.

Vaccine Information Statements (VIS)

The U.S. National Childhood Vaccine Injury Act (NCVIA) requires all health-care providers in the United States who administer measles-mumps-rubella (MMR) vaccine to provide a copy of the relevant vaccine information statement to either an adult vaccinee, or in the case of a minor, to a parent or legal representative. Health-care providers are not required to obtain the signature of the patient, parent, or legal representative acknowledging receipt of the vaccine information statements. However, to document that the vaccine information statement was given, health-care providers must note in each patient's permanent medical record at the time a vaccine information statement is provided the date printed on the vaccine information statement and the date the vaccine information statement is administered to the vaccine recipient, parent, or legal representative. The U.S. National Childhood Vaccine Injury Act also requires that health-care providers note the following information in the patient's permanent medical record:

- The date of administration of the vaccine.
- The manufacturer and lot number of the vaccine.
- The name and address of the health-care provider administering the vaccine (i.e., the address where the record is kept; if vaccinations are administered in a shopping mall, for example, the address should be the clinic where the permanent record will reside).

Reporting Adverse Events

The U.S. National Vaccine Injury Act of 1986 requires physicians and other health-care providers who administer vaccines to maintain permanent immunization records and to report occurrences of adverse events for selected vaccines. Serious adverse events (i.e., all events requiring medical attention), regardless of whether they are suspected to have been caused by vaccine, should be reported to the Vaccine Adverse Event Reporting System (VAERS). Vaccine Adverse Event Reporting System forms and instructions are available by calling the 24-hour Vaccine Adverse Event Reporting System information recording at (800) 822-7967 (United States only). Information is also available from the Vaccine Adverse Event Reporting System Web site (the Vaccine Adverse Event Reporting System [VAERS] is a Cooperative Program for Vaccine Safety of the U.S. Food and Drug

Administration [FDA] and the U.S. Centers for Disease Control and Prevention [CDC]).

Rubella Prevention and Control Among Women of Childbearing Age

Guidelines for rubella prevention and control among women of childbearing age differ depending on the likelihood of exposure to rubella. Identifying women who could have been exposed is critical so they can receive appropriate testing and follow-up. Guidelines for testing and follow-up for all women of childbearing age, pregnant women for whom rubella exposure is unlikely, and pregnant women who might have been exposed to rubella are outlined in the sections below.

All Women of Childbearing Age

Health-care providers who treat women of childbearing age should routinely determine rubella immunity and vaccinate those who are susceptible and not pregnant. Proof of immunity can be either a verified record of vaccination or a positive immunoglobulin G antibody serologic test. Rubella-susceptible women who (a) do not report being pregnant, (b) are not likely to become pregnant in the next three months, and (c) do not have other contraindicating conditions should be vaccinated. Before vaccination, each patient should be counseled to avoid pregnancy for 3 months after vaccination because of the theoretical risk for vaccine virus affecting the fetus. Because routine pregnancy screening is not recommended before rubella vaccination, patients should be counseled regarding the theoretical risk to the fetus from inadvertent vaccination of a pregnant woman.

Pregnant Women Without Likely Exposure

Even when no outbreaks have been reported and no rubella exposure has occurred, health-care providers should routinely conduct a rubella immunoglobulin G test for all pregnant women at the earliest prenatal visit. A positive rubella immunoglobulin G antibody test indicates rubella immunity, and health-care providers can assume that immunity was acquired before pregnancy. Women who are found to be susceptible should be monitored for signs of rubella during pregnancy and vaccinated postpartum. Susceptible pregnant women should be advised to avoid contact with persons with rash illness.

An immunoglobulin M test should not be used to determine rubella immune status; immunoglobulin M is used to diagnose acute and recent rubella infection. The TORCH (i.e., toxoplasmosis, rubella, cytomegalovirus, and herpes) panel includes a test for rubella immunoglobulin G antibodies as well as a test for rubella immunoglobulin M antibodies. Because of the potential for false-positive immunoglobulin M results, a toxoplasmosis, rubella, cytomegalovirus, and herpes panel should not be used to determine rubella immunity. Rubella immunoglobulin M testing should be performed on pregnant women who report symptoms of rubella or susceptible pregnant women who might have been exposed to rubella to rule out acute or recent infection.

Screening and Follow-Up of Pregnant Women Who Might Have Been Exposed to Rubella

Because the consequences of rubella infection during pregnancy are serious, every effort must be made to identify all women of childbearing age exposed to a person with confirmed, probable, or suspected rubella. Women found to be susceptible and not pregnant should be vaccinated as outlined previously (see the section titled "All Women of Childbearing Age," above). Susceptible household contacts of pregnant women should also be vaccinated.

All exposed pregnant women should be screened to determine if they (a) were infected during pregnancy, (b) are susceptible, or (c) were immune before pregnancy. Because of the seriousness of congenital rubella infection, immunity must be documented by a verified, dated record of a positive serologic test. Pregnant women without documented immunity should be tested for the presence of rubella immunoglobulin G and immunoglobulin M antibodies as outlined in this section. Identifying susceptible pregnant women is critical, so they can be isolated from further exposure, monitored for infection, and vaccinated postpartum. Pregnant women with evidence of infection during pregnancy should be evaluated to verify rubella infection and determine gestational age at time of infection, if possible, to assess the possibility of risk to the fetus.

Immunoglobulin (IG) does not prevent rubella or mumps infection after exposure and is not recommended for that purpose. Administration of immunoglobulin after exposure to rubella will not prevent infection or viremia, but might modify or suppress symptoms and create an unwarranted sense of security. Therefore, immunoglobulin is not recommended for routine postexposure prophylaxis of rubella in early pregnancy or any other circumstance. Infants with congenital rubella have been born to women who received immunoglobulin shortly after exposure. Administration of immunoglobulin should be considered only if a pregnant woman who has been exposed to rubella will not consider termination of pregnancy under any circumstances. In such cases, intramuscular administration of 20 mL of immunoglobulin within 72 hours of rubella exposure might reduce, but will not eliminate, the risk for rubella.

During an outbreak, the following steps should be taken to evaluate and follow up with pregnant women who had contact with a person with confirmed, probable, or suspected rubella:

- Use documented serologic test results to verify immunity. If unavailable, conduct rubella immunoglobulin G and immunoglobulin M antibody testing regardless of symptom history. Pregnant women who are exposed to rubella and who do not have documented proof of immunity should be tested for rubella-specific immunoglobulin M antibodies to identify recent infection. Because 20% to 50% of rubella cases are asymptomatic, this testing policy is crucial to assess the possibility of risk to the fetus. Another way to identify recent infection is to detect a significant rise in paired immunoglobulin G serum. A single positive Immunoglobulin G test indicates rubella immunity, but does not give information regarding the timing of the infection. However, a significant rise in immunoglobulin G antibody (determined by testing paired sera) or positive immunoglobulin M antibody test indicates recent infection.
- Recommend restricting activities to avoid exposure while waiting for serologic test results. During this time, pregnant women should be excluded from activities (e.g., work or school) that present the possibility of exposure to persons with confirmed or suspected cases of rubella. Pregnant women found

to be susceptible to rubella should avoid these settings for 6 weeks (two incubation periods) after the onset of symptoms of rubella in the last patient for whom rubella cannot be ruled out.

- Evaluate exposed pregnant women with positive immunoglobulin G titers and negative immunoglobulin M to determine if they acquired immunity before pregnancy or infection during pregnancy. Women without previously documented immunity who were exposed during pregnancy and >6 weeks before immunoglobulin M testing could test negative for immunoglobulin M antibodies, which are normally not detectable more than 6 weeks after infection. Thus, a negative rubella immunoglobulin M antibody assay does not rule out infection during pregnancy. The dates of the pregnancy, possible exposures, test(s), and history of rash illness should be considered in assessing the possibility of risk to the fetus.
- Evaluate pregnant women with confirmed rubella to assess risk to the fetus. Rubella infection during the first 3 months of pregnancy is associated with the greatest risk for congenital rubella infection, and up to 90% of infants born to mothers infected during the first 11 weeks of gestation will develop congenital rubella syndrome. Infection late in the first half of pregnancy is more likely to result in hearing impairment and less likely to be associated with other defects. Although not likely to result in congenital rubella syndrome, rubella infection late in pregnancy can result in congenital rubella infection only.
- Pregnant women with negative immunoglobulin G and negative immunoglobulin M on first testing should be retested in 10 to 14 days; the first specimen should be reanalyzed along with the second specimen. A significant rise in immunoglobulin G or positive immunoglobulin M indicates recent infection. If a susceptible pregnant woman continues to be directly exposed to rubella, repeat tests of paired sera in 10 to 14 days to determine if infection occurs, then every 3 to 4 weeks if exposure continues. Testing can be performed earlier if pregnancy outcome might be influenced. Evaluate the infant on delivery for signs of congenital rubella syndrome, and vaccinate the mother postpartum.
- Recommend restricting activities for susceptible women (i.e., those without detectable immunoglobulin G and immunoglobulin M antibodies), obtain follow-up serologic testing, and vaccinate after delivery. Susceptible pregnant women should be excluded from activities (e.g., work or school) that present the possibility of exposure to persons with confirmed or suspected cases of rubella. Pregnant women found to be susceptible should avoid these settings for six weeks (two incubation periods) after the onset of symptoms of rubella in the last patient for whom rubella cannot be ruled out. Household contacts or other ongoing contacts without documented rubella immunity should be vaccinated.
- Evaluate asymptomatic, exposed pregnant women with documented history of previous rubella immunity. Rubella reinfection is rare but has been documented. Women with documentation of previous rubella immunity who are exposed to rubella during pregnancy should consult their physicians. After discussing the potential for reinfection, physicians might recommend acute- and convalescent-phase immunoglobulin G antibody testing or an immunoglobulin M antibody test to document whether reinfection has occurred. However, the potential for false-positive immunoglobulin M tests exists, and the potential risks and benefits of testing should be considered.
- Counsel pregnant women with documentation of previous immunity to seek medical attention promptly if rubella-like symptoms appear. Any pregnant woman with documented immunity and rubella-like symptoms should be

immediately evaluated by a physician to diagnose the symptoms and ensure the health of the mother and fetus.

Surveillance for Congenital Rubella Syndrome

Consequences of congenital rubella infection during pregnancy include abortion, miscarriage, stillbirth, and a pattern of birth defects called congenital rubella syndrome. The most common congenital defects related to congenital rubella syndrome are cataracts, heart defects, hearing impairment, and developmental delay. Other less specific signs and symptoms of congenital rubella syndrome include purpura, hepatosplenomegaly, jaundice, microcephaly, meningoencephalitis, and radiolucent bone disease.

Pregnant women with known rubella exposure should receive follow-up care. Surveillance for congenital rubella infection and congenital rubella syndrome should be implemented when confirmed or probable rubella cases are documented in a setting where pregnant women might have been exposed. The following steps are recommended to achieve these goals:

- Follow the outcome of pregnancy for pregnant women with confirmed or suspected rubella infection and for susceptible pregnant women with rubella exposure. A state or local registry of pregnant women with confirmed or suspected rubella should be established to record pregnancy outcomes (e.g., abortion, stillbirth, congenital rubella-associated defects) and laboratory evaluation of infants. Because hearing impairment, cataracts, and heart defects are common among infants with congenital rubella syndrome, hearing and vision evaluations for infants born to susceptible, pregnant women exposed to rubella could help identify cases and aid early diagnosis and intervention.
- Educate and heighten awareness among health-care providers. Health-care providers in the area of an outbreak should be made aware of the potential for congenital rubella syndrome births in their facilities and given information regarding the physical manifestations of congenital rubella syndrome and appropriate laboratory testing for infants with suspected congenital rubella syndrome. The classic presentation for congenital rubella syndrome is cataracts, hearing impairment, and congenital heart disease (especially patent ductus arteriosus or peripheral pulmonic stenosis). Some conditions associated with congenital rubella syndrome (e.g., hearing impairment and developmental delay) might not be apparent at birth.

The following steps are recommended for follow-up and surveillance for congenital rubella syndrome and congenital rubella infection only cases:

- Discuss appropriate isolation procedures for infants with congenital rubella syndrome and congenital rubella infection only with health-care providers. Only persons immune to rubella should have contact with these infants. Children with congenital rubella syndrome should be presumed infectious at least through age 1 year unless nasopharynx and urine cultures are negative for virus after age 3 months. Some authorities suggest that an infant with congenital rubella syndrome should be considered infectious until two cultures of clinical specimens obtained one month apart are negative for rubella virus.

- Use universal newborn hearing screening programs to help detect congenital rubella syndrome, where available. Approximately 50% of states have such programs, some of which use a combination of evoked otoacoustic emissions and auditory brainstem response to identify hearing impairment in newborns. Because hearing impairment is the most common single defect associated with congenital rubella syndrome, newborns who fail hearing screening tests should be tested for rubella-specific immunoglobulin M antibodies to rule out congenital rubella syndrome.
- Confirm the congenital rubella syndrome or congenital rubella infection only diagnosis with laboratory testing (see the section titled "Laboratory Diagnosis of Congenital Rubella Syndrome and Congenital Rubella Infection" in the original guideline document).
- Report all congenital rubella syndrome and congenital rubella infection only cases to the state health department as soon as they are suspected, even though laboratory confirmation might be pending. State health departments should then report cases to the U.S. Centers for Disease Control and Prevention's Rubella Activity at (404) 639-8230 (United States only). Cases are then entered into the National Congenital Rubella Syndrome Registry. The following data are epidemiologically important and should be collected during case investigations (additional information can be collected at the direction of the state health department):
    - Demographic information
    - Maternal history, including (a) date of rubella vaccination(s), (b) dates and results of previous serologic tests for rubella immunity, (c) history or documentation of rubella infection during pregnancy, (d) history of pregnancies inside and outside the United States, (e) country of birth and length of residence in the United States, and (f) history of exposure to rubella and travel
    - Clinical details (e.g., cataracts, hearing impairment, developmental delay, type of congenital heart defect, meningoencephalitis, microcephaly)
    - Laboratory information, including types and results of laboratory testing performed on both mother and child
- Recommend consultation with specialists for infants with congenital rubella syndrome, as appropriate, based on clinical manifestations.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Reduction in the incidence of outbreaks of rubella, rubella in pregnant women, congenital rubella syndrome, and congenital rubella infection
- Reduction in the rate of morbidity and mortality due to outbreaks of rubella, rubella in pregnant women, congenital rubella syndrome, and congenital rubella infection

Subgroups Most Likely to Benefit:

The incidence of rubella and congenital rubella syndrome is higher among foreign-born (notably those from Mexico or Central America) persons and infants born to foreign-born women.

POTENTIAL HARMS

Allergic reaction to measles-mumps-rubella (MMR) vaccine.

CONTRAINDICATIONS

CONTRAINDICATIONS

The following is a summary of contraindications and precautions for administration of measles-mumps-rubella (MMR) vaccine. For more detailed information, consult the 1998 U.S. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) statement on measles-mumps-rubella vaccination (MMWR Morb Mortal Wkly Rep 1998 May 22;47[RR-8]:1-57; see the related National Guideline Clearinghouse [NGC] Guideline Summary):

Allergic Reactions

Measles-mumps-rubella (MMR) vaccine should not be administered to persons who have experienced severe allergic reactions to a previous dose of a rubella-containing vaccine or to a vaccine component (e.g., gelatin or neomycin). Allergy to egg is not a contraindication.

Pregnancy

Measles-mumps-rubella (MMR) vaccine should not be administered to women known to be pregnant or attempting to become pregnant. Because of the theoretical risk to the fetus, women should be counseled to avoid becoming pregnant for 3 months after receipt of a rubella-containing vaccine. If a pregnant woman is vaccinated or becomes pregnant within 3 weeks after receipt of vaccine, she should be counseled regarding the theoretical basis of concern for the fetus. However, receipt of rubella-containing vaccine during pregnancy should not ordinarily be a reason to consider termination of pregnancy. Women who are susceptible to rubella and not vaccinated because they are pregnant or might become pregnant within the next 3 months should be advised regarding the potential risk for congenital rubella syndrome and the importance of being vaccinated as soon as they are no longer pregnant.

From January 1971 through April 1989, the U.S. Centers for Disease Control and Prevention followed to term 321 known rubella-susceptible women who were

vaccinated within 3 months before or 3 months after conception. Ninety-four women received HPV-77 or Cendehill vaccines, one received vaccine of unknown strain, and 226 received RA 27/3 vaccine (the only rubella vaccine presently used in the United States). None of the 324 infants born to these mothers had malformations compatible with congenital rubella infection (CRI), but five had evidence of subclinical rubella infection, two of whom were exposed to RA 27/3 vaccine. Based on these data, the estimated risk for serious malformations attributable to RA 27/3 vaccine ranges from zero to 1.6%. Breast-feeding is not a contraindication to receiving measles-mumps-rubella vaccine.

Immunodeficiency

Measles-mumps-rubella (MMR) vaccine should not be administered to persons with severe immunodeficiency from any cause. Persons with mild immunosuppression (e.g., from asymptomatic human immunodeficiency virus [HIV] infection or short-term or low-dose steroid use) may be vaccinated.

Illness

Health-care providers should evaluate whether to administer measles-mumps-rubella (MMR) vaccine to:

- Persons with moderate or severe illness. Minor illnesses (e.g., otitis media or mild upper respiratory tract infection) are not contraindications for receipt of vaccine.
- Persons with history of thrombocytopenia. The decision to vaccinate should depend on the benefits of immunity to measles, mumps, and rubella compared with the risks for recurrence or exacerbation of thrombocytopenia either after vaccination or during natural infection with measles or rubella.
- Persons who have received high doses of immunoglobulins. Recent evidence indicates that high doses of immunoglobulins can inhibit the immune response to rubella vaccine for $\geq$3 months.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The recommendations can be used in settings beyond those discussed in the original guideline document.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Control and prevention of rubella: evaluation and management of suspected outbreaks, rubella in pregnant women, and surveillance for congenital rubella syndrome. MMWR Recomm Rep 2001 Jul 13;50(RR-12):1-23. [22 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

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GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

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GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML version
- Portable Document Format (PDF) version

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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